



PATIENT INFORMATION SHEET ON FOUNDATIONCORE (FOR CLINICAL TRIAL PARTICIPANTS ONLY)

FMI Tests



Patient Information about the Processing of Personal Data

As part of your participation in a clinical trial, your treating physician has ordered a molecular profiling test to analyse your blood (which may include bone marrow) and/or tissue specimen (as required for your test) in order to detect genomic biomarkers, such as gene mutations, specific to your tumour. The appropriate diagnostic test selected by your physician is one of the tests at the top of this document (“FMI Tests”).

As part of your participation in the clinical trial, you have the choice to provide your consent to the processing of your pseudonymised data for research and scientific purposes (as outlined below) by Foundation Medicine GmbH, Nonnenwald 2, 82377 Penzberg, Germany (“FMI GmbH”) and Foundation Medicine Inc., 150 Second Street, Cambridge, MA 02141, USA (“FMI Inc.”) as joint controllers. FMI GmbH and FMI Inc. will jointly process your personal data on systems and applications operated by FMI Inc. FMI GmbH and FMI Inc. are hereinafter, collectively, referred to as “FMI”.

Your consent to the processing of your personal data as described in this Patient Information Sheet is voluntary, and you can freely decide whether you wish to grant your consent.

Use of your Pseudonymised Data for Research and Scientific Purposes

If you give your consent, your pseudonymised data will be used by FMI – in addition to performing the applicable FMI Test on behalf of the trial Sponsor- for research and scientific purposes, including in a commercial context, to improve the understanding of tumour genesis and tumour progression and to facilitate the improvement, validation and development of new diagnostic and therapeutic approaches for the treatment of genetic diseases. Your pseudonymised data may include the following: Order-ID, date of birth, gender, diagnosis (stage), specimen site, specimen-ID (identifier of the blood/tissue specimen), date of specimen collection, international classification of the disease (ICD-10 Code), status of transplant, contact information of your treating physician and pathologist, scanned tissue slides, sequencing data and supplementary molecular information (if applicable). If you give your consent, you agree that FMI GmbH and FMI Inc. will, as joint controller:

- store any data received and/or generated as part of providing the FMI Tests together with the prepared report for a maximum period of 10 years after the date of the release of the FMI test report to your treating physician. FMI will store your data only in **pseudonymised** form (under an Order-ID) and will not receive or store your name or other information which would be directly attributable to your person.
- process such data in pseudonymised or anonymised form, including in a commercial context, for research and scientific purposes, including statistical analysis, to further understand the causes for tumour genesis and tumour progression as well as to improve, validate and/or develop new diagnostic and therapeutic approaches for the treatment of genetic diseases, including to improve the Services FoundationOne CDx, FoundationOne Liquid CDx and FoundationOne Heme; and
- disclose such data for the above purposes in pseudonymised or anonymised form, including in a commercial context, to external academic, industrial or other collaboration partners.

Your personal data will not be used for any other purposes, except in fully **anonymised** form (i.e. where the information has been rendered anonymous so that it can no longer in any way (whether directly nor indirectly) be attributed to your person).

Data Transfer Protections

Your pseudonymised data will be transmitted to FMI Inc. in the US, and thus to a country outside the EU/EEA and UK, the laws of which may not provide for the same level of data protection as considered adequate in the EU and/or UK.

This triggers certain risks for the protection of your personal data, including that it may be more difficult to enforce your data protection rights as a data subject and that your pseudonymised personal data may be subject to access requests under applicable US law by public authorities which may have more extensive powers than the authorities in the EU/EEA and/or UK. To ensure that your data are adequately protected as required by EU and UK data protection laws, FMI have entered into contractual safeguards on the basis of the EU Standard Contractual Clauses (according to Art. 46 EU GDPR) between FMI GmbH and FMI Inc. and implemented further supplementary measures, including a privacy by design concept that ensures only pseudonymised data not directly attributable to your person will be transferred to and processed and stored by FMI Inc. or its further subcontractors in the US. To the extent FMI may accidentally receive data in identifiable form (such as your name in a report), FMI will redact such information upon receipt.

To the extent your pseudonymised data is transferred to FMI Inc. directly by your treating physician or pathologist (such as in the case of an order of FoundationOne Liquid CDx) prior to the time that FMI GmbH is able to perform the laboratory service portion of the FoundationOne Liquid CDx test, FMI Inc. will protect the data received equally under the EU Standard Contractual Clauses entered into with FMI GmbH.

FMI may further engage technical service providers as processors for the hosting and operation of its databases, portals and

applications. These service providers may be located in the EU/EEA or the US. In case of service providers in the US, FMI will ensure that appropriate safeguards are in place to provide for an adequate level of data protection, such as by entering into data transfer agreements with the applicable service provider on the basis of the EU Standard Contractual Clauses or standard data protection clauses adopted or approved by the European Commission (Art. 46 GDPR).

You can find out more information about the safeguards implemented by FMI, including how to obtain a copy of them, by contacting FMI at the contact details set out below.

Contact Details; Data Protection Officer

FMI GmbH: Foundation Medicine GmbH, Nonnenwald 2, 82377 Penzberg, Germany
FMI Inc.: Foundation Medicine Inc., 150 Second Street, Cambridge, MA 02141, USA

The data protection and privacy officers of FMI are your points of contact regarding any questions, suggestions or complaints concerning the processing of your personal data as described in this Patient Information Sheet.

Their contact details are as follows:

Data protection officer of FMI GmbH: Foundation Medicine GmbH, Nonnenwald 2, 82377 Penzberg, Germany; dpo.fmi-germany@foundationmedicine.com, Phone: +49 (8856)905-3715

Data protection officer of FMI Inc.: Foundation Medicine, Inc., 150 Second Street, Cambridge, Massachusetts 02141, dpo.fmi-cambridge@foundationmedicine.com, Phone: +1(617) 413-7313

Security

FMI take appropriate technical and organisational measures to protect your personal data against accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.

Your Rights

You have the right, in accordance with applicable data protection law:

- to request information about the data processed about you, and to obtain a copy of such data (right of access);
- to obtain the rectification of inaccurate data or, taking into account the purposes of the processing, request the completion of incomplete data (right to rectification);
- to obtain the erasure of personal data to the extent one of the grounds provided for by statutory law applies (right to be forgotten); - to the extent the statutory requirements are fulfilled, to obtain the restriction of processing of your data (right to restriction of processing); - to the extent the statutory requirements are fulfilled, to receive any personal data you provided to FMI in a structured, commonly used and machine-readable format and to transmit those data to another controller or, where technically feasible, have the data transmitted (right to data portability); and
- not to be subject to an automated individual decision making if the statutory requirements are not fulfilled. An automated individual decision making is not taking place.

You further have the right to:

- object, on grounds relating to your particular situation and in accordance with applicable law, to any processing of your personal data based on the ground that the processing is necessary for purposes of legitimate interests pursued by FMI (right to object);
- withdraw your consent at any time without affecting the lawfulness of processing based on consent before its withdrawal; and
- lodge a complaint with a data protection authority, in particular the data protection authority competent for your place of habitual residence or place of the alleged infringement.

To exercise your rights, please contact your treating physician. You may also contact either of the data protection officers named above. Please note, however, that FMI generally only receives pseudonymised data. Therefore, FMI cannot ensure it will be able to verify your authorisation or identify your person or the data concerning you in the context of your requests without receiving additional information from you and your treating physician. Therefore, in order to effectively exercise your rights (and to avoid having to identifying yourself to FMI), please contact your treating physician directly, even if you wish to exercise your rights against FMI GmbH and/or FMI Inc.

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